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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
CHISM, BILLY D

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,129	Applicant(s) UENO, RYUJI	
	Examiner B. Dell Chism	Art Unit 1654	

-- Th MAILING DATE of this communication app ars on th cover sheet with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *5-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is the first action on the merits. Claims 1-10 are pending and are under consideration by the Examiner.

Information Disclosure Statement

The IDS file 06/25/2001 (Paper No. 3) has been considered and a signed copy of the PTO 1449 form is attached hereto.

Objections to Specification

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. The specification lacks many of the required articles ("a", "the", etc.).

The use of the trademark FK506 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for the indefinite recitation of "disorder." The specification fails to teach the metes and bounds of "visual cell disorder." It is thus unclear if the claim is drawn to a specific disorder or if the claim encompasses numerous undefined visual disorders.

Claim 4 is rejected because the claim contains a trademark/trade name, FK506. There a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product; the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe and, accordingly, the identification/description is indefinite.

Claims 2-3 and 5-8 are rejected for depending from rejected claim 1.

Claim 10 provides for the use of interleukin 2 inhibitor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Applicants should follow the same format as in claim 9.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of retinopathy, does not reasonably provide enablement for other visual cell function disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman,

230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a product and method for the treatment of visual cell function disorders via administration of an interleukin-2 inhibitor.

The state of the prior art and the predictability or lack thereof in the art: The prior art does not teach the predictability of "blanket" treatment of all visual cell function disorders by the administration of an interleukin-2 inhibitor, nor does the art teach "blanket" treatment by any compound or composition that would encompass all disorders.

The amount of direction or guidance present and the presence or absence of working examples: Given the lack of teachings regarding predictability found in the art, detailed teachings are required to be present in the disclosure in order for the skilled artisan to be able to treat all visual cell function disorders by administration of an interleukin-2 inhibitor. These teachings are absent. The teachings found in the present specification are limited to general statements that the method of the invention may be employed to treat visual cell function disorders, however, the only examples of proper direction or guidance is for the treatment of retinopathy (see page 13-15). There are no teachings and no guidance in the disclosure addressing how to make and administer an interleukin-2 inhibitor for treatment of all visual cell function disorders (i.e., blindness

The breadth of the claims and the quantity of experimentation needed: Because the art does not teach "blanket" treatment of all or most visual cell function disorders by one therapeutic compound, and because the disclosure is devoid of any teachings or guidance as to how to overcome the lack of teachings regarding predictability, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Morice *et al.* 1993, (J. of Biol. Chem, Vol. 268, No. 5, pp. 3734-3738), further anticipated by Ryffel *et al.*

1995 (Immunopharmacology, Vol. 30, pp. 199-207), and further anticipated by Tsuboi *et al.* 1994 (Molecular Biology of the Cell, Vol. 5, pp. 119-128). Morice *et al.* discusses the ability of the macrolide, rapamycin (RAPA), to inhibit IL-2-induced T-cell proliferation via inhibition of $p34^{cdc2}$ kinase activation, and where upon the broadest interpretation of the claims, the interleukin-2 is inhibited from effecting T-cell proliferation.

Ryffel *et al.* discusses the ability of cyclosporin A and tacrolimus to inhibit T-lymphocyte activation at the gene transcription level and they inhibit the protein expression as well. They further demonstrate rapamycin's ability to inhibit interleukin-2 receptor upregulation, however, rapamycin does not inhibit transcription, as is the case with CsA and tacrolimus.

Tsuboi *et al.* teaches cyclosporin A and FK506 as inhibitors of interleukin-2.

9. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kulkarni *et al.* 1993 (0 532 862 A1). Kulkarni *et al.* teaches a medicament for the treatment of ocular inflammation and the macrolide, rapamycin, in a component of that medicament. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Because the process steps of administering an interleukin-2 inhibitor are the same regardless of whether the purpose is to inhibit interleukin-2 or to treat ocular inflammation (Ex parte Novitski, 26 USPQ 1391), the instant process claims would inherently inhibit interleukin-2 and treat ocular inflammation. Claim 10 is rejected as a method claim. Under the principles of

inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. (MPEP § 2112.02). The preceding rejection is based on the judicial precedent following *In re Fitzgerald*, 203 USPQ 594 because the prior art is silent with regard to treatment of "visual cell function disorder".

Conclusions

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
10 March 2003

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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